

2. This case belongs in federal court, just like the identical complaint that Plaintiff's lawyers filed a day earlier in federal court in Illinois. *See Curran v. Bayer HealthCare LLC and Merck & Co.*, No. 17-cv-07930, Dkt. No. 1 (N.D. Ill. Nov. 2, 2017). As set forth more

fully below, this Court has federal-question jurisdiction. The Complaint alleges that an over-the-counter (“OTC”) monograph drug, Coppertone Sport SPF 30 Spray and Lotion, fails to meet specific and comprehensive federal standards for claiming “SPF 30” protection. *See* Ex. A (Complaint). Plaintiff’s case depends entirely on the bald (and incorrect) assertion that the products do not satisfy these federal standards, which were promulgated by the federal Food and Drug Administration (“FDA”). *Id.*; Ex. B (FDA SPF Sunscreen Regulation).

3. Plaintiff thus pleads a violation of federal law on the face of his Complaint, and his right to relief depends completely on the scope, interpretation, and application of federal law. Moreover, the exercise of jurisdiction will not disrupt any federal-state balance, because the case depends entirely on the federal standard. Under well-established precedent, there is federal question jurisdiction. *Grable & Sons Metal Prods., Inc. v. Darue Eng’g & Mfg.*, 545 U.S. 308, 312-14 (2005); *see also Menoken v. McNamara*, 213 F.R.D. 193, 196-98 (D.N.J. 2003) (affirming grant of removal on grounds that case presented a federal question because federal law was an essential element of plaintiffs case).

4. In addition to this Notice of Removal, Bayer intends to file a Motion to Dismiss that will demonstrate that all of Plaintiff’s claims are preempted and/or otherwise without merit.

#### **I. THE PROCEDURAL REQUIREMENTS OF REMOVAL ARE MET.**

5. Pursuant to 28 U.S.C. § 1446(a), true and correct copies of all process, pleadings, orders and other documents filed in the state court action are attached as Exhibit A.

6. Plaintiff’s Complaint was served on Bayer HealthCare LLC, on November 20, 2017, and on Merck & Co., Inc., on November 20, 2017. This Notice is timely because it is filed within 30 days of the service of a complaint upon the defendants. *See* 28 U.S.C. § 1446(b)(1); *Murphy Bros., Inc. v. Michetti Pipe Stringing, Inc.*, 526 U.S. 344, 354 (1999) (30-day time limit for removal runs from date of formal service of the initial complaint).

7. The United States District Court for the District of New Jersey embraces the place where the state court action is now pending and is therefore a proper forum. *See* 28 U.S.C. §§ 110, 1441(a).

8. All Defendants consent to removal. *See* 28 U.S.C. §§ 1441(c)(2), 1446(b)(2)(A). A copy of Merck's consent to removal is attached hereto as Exhibit C.

9. A copy of this Notice of Removal is being served on Plaintiff, and a copy is being filed with the state court. *See id.* § 1446(d). A copy of the Notice of Filing of Notice of Removal to be filed with the state court is attached hereto as Exhibit D.

10. If any questions about this removal arise, Defendants respectfully request the opportunity to present briefing and oral argument in support of removal.

**II. REMOVAL IS PROPER BECAUSE THIS COURT HAS SUBJECT MATTER JURISDICTION PURSUANT TO 28 U.S.C. §§ 1331 AND 1441.**

11. Federal-question jurisdiction in this context turns on whether “a state-law claim necessarily raise[s] a stated federal issue, actually disputed and substantial, which a federal forum may entertain without disturbing any congressionally approved balance of federal and state judicial responsibilities.” *Grable*, 545 U.S. at 314; *see also Manning v. Merrill Lynch Pierce Fenner & Smith, Inc.*, 772 F.3d 158 (3d Cir. 2014) (“federal issue is: (1) necessarily raised, (2) actually disputed, (3) substantial, and (4) capable of resolution in federal court without disrupting the federal-state balance approved by Congress”). *Grable* and *Manning* “capture[] the commonsense notion that a federal court ought to be able to hear claims recognized under state law that nonetheless turn on substantial questions of federal law, and thus justify resort to the experience, solicitude, and hope of uniformity that a federal forum offers on federal issues.” *Grable*, 545 U.S. at 312.

12. These jurisdictional standards are plainly met here. Plaintiff's claim turns entirely on a specific and comprehensive federal testing standard, promulgated and enforced by the FDA. 21 C.F.R. § 201.327;

<https://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/Over-the-CounterOTCDrugs/StatusofOTCRulemakings/ucm072134.htm>

(last visited December 8, 2017) (cataloging the extensive history of FDA regulations of sunscreen). Plaintiffs allege a federal violation on the face of the complaint, that alleged violation is actually disputed and substantial, and resolving it would not disrupt any federal-state balance.

**A. Plaintiff's Right To Relief Depends On The Resolution Of Substantial And Disputed Federal Questions.**

13. All of Plaintiff's claims against Bayer turn on the meaning and requirements of federal regulations and whether Bayer did or did not violate federal law. Ex. A (Compl.).

Plaintiff alleges, for example, that:

- a. "Plaintiff conducted his own independent testing of Coppertone Sport High Performance SPF 30 sunscreen spray and lotion, utilizing the methodology for SPF testing mandated by the FDA." Compl. ¶ 39.
- b. "The independent testing performed by Plaintiff was conducted in compliance with all FDA testing methods embodied in FDA Final Rule, 21 CFR Parts 201 and 310, Federal Register/Vol. 76, No. 117/Friday, June 17, 2011/ Rules and Regulations, including 21 CFR 201.327." Compl. ¶ 40.
- c. "The Coppertone website further asserts: 'Because we're committed to quality, excellence, innovation and truth in labeling, our products must pass rigorous scientific testing – one that goes above and beyond what the FDA requires – because its on your favorite store shelf.' Such testing necessarily would have made Defendants aware that their Coppertone Sport High Performance SPF 30 sunscreen spray and lotion do not have an SPF rating of 30, as claimed on the products' labels." Compl. ¶ 53.
- d. "All of Plaintiff's state law claims are based on misleading statements that violate FDA regulations." Compl. ¶ 68.

14. The alleged federal violations are thus front and center, and Plaintiff's right to relief "necessarily turn[s] on" their resolution. *Manning*, 772 F.3d at 163. Indeed, federal law *requires* that to be the case. The FDCA expressly preempts "any requirement" imposed by state law "that is different from or in addition to, or that is otherwise not identical with, a requirement under this chapter [regulating OTC drugs]." 21 U.S.C. § 379r. To the extent that Plaintiff's state-law causes of action claim that Defendants breached duties "different from, or in addition to" federal requirements, therefore, those claims are preempted. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 330 (2008); *Grisvold v. Merck*, No. 3:14-cv-01371, 2014 WL 6765718, at \*1 (S.D. Cal. Nov. 25 2014) (holding that the FDCA's express preemption provision applies to OTC monograph drugs including sunscreen); *Burke v. Weight Watchers International, Inc.*, 983 F.Supp.2d 478, 480, 483 (D. N.J. Oct. 17, 2013) (granting motion to dismiss on preemption grounds because conclusory allegation of regulatory compliance for testing was "insufficient to allege a violation of the FDCA").

15. What that means is simple: Plaintiff cannot succeed on his claims *unless* he shows that Defendants violated *federal* requirements listed in complex and highly technical *federal* regulations and subject to *federal* enforcement. *See, e.g.*, 21 CFR 201.327; FDA, Guidance for Industry, Enforcement Policy – OTC Sunscreen Drug Products Marketed Without an Approved Application, at 6 (June 2011). In short, a substantial federal question is necessarily raised and actually disputed.

**B. Federal Jurisdiction Will Not Disrupt the Federal-State Balance.**

16. The exercise of federal-question jurisdiction will not disrupt the careful balance between federal and state law that Congress has created. There is a comprehensive and rigorous regulatory scheme, substantial federal review and oversight of the product at issue, and a broad

express-preemption statute. Recognizing federal-question jurisdiction would thus ensure that important federal issues of law are decided in federal court with no drastic effect on the federal-state division of labor beyond upholding the federal laws that Congress and the FDA have adopted. *See Grable*, 545 U.S. at 315; *Reuter*, 996 F. Supp. 2d at 680. As a result, the exercise of federal question jurisdiction is necessary and appropriate.

### **JURY DEMAND**

Pursuant to Federal Rule of Civil Procedure 38, Bayer HealthCare LLC, hereby demands a jury trial on all triable issues in this action.

### **CONCLUSION**

WHEREFORE, Notice is given that this action is removed from the Superior Court of New Jersey Camden County to the United States District Court for the District of New Jersey.

DATED: DECEMBER 19, 2017

Respectfully submitted,

/s/ Christopher E. Torkelson

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**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

ANDREW ROSEMAN, on behalf of himself  
and all other similarly situated,

Plaintiff,

V.

BAYER HEALTHCARE LLC and MERCK &  
Co., Inc.,

Defendants.

Case No. \_\_\_\_\_

**Document Filed Electronically**

STATEMENT PURSUANT TO LOCAL  
CIVIL RULE 10.1(a)

Pursuant to Local Civil Rule 10.1(a), attached hereto as Exhibit A is a service list that sets forth the names and address of each party, as well as known counsel of record, in the above-captioned action.

DATED: DECEMBER 19, 2017

Respectfully submitted,

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**Exhibit A**

**SERVICE LIST**

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